

Message Text

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ORIGIN HEW-06

INFO OCT-01 ARA-10 EA-09 ISO-00 OES-05 COME-00 AID-05 /036 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/OIH: MACODDING

ARA/EX:KDACKERMAN(INFO)

EA/IMS:WSSHEPARD(INFO)

----- 049591

P 272247Z FEB 76

FM SECSTATE WASHDC

TO AMEMBASSY SANTIAGO PRIORITY

AMEMBASSY SANTO DOMINGO PRIORITY

AMEMBASSY SAN SALVADOR PRIORITY

AMEMBASSY GUATEMALA PRIORITY

AMEMBASSY TEGUCIGALPA PRIORITY

AMEMBASSY PORT AU PRINCE PRIORITY

AMEMBASSY KUALA LUMPUR PRIORITY

AMEMBASSY MANAGUA PRIORITY

AMEMBASSY LIMA PRIORITY

AMEMBASSY SINGAPORE PRIORITY

AMEMBASSY MONTEVIDEO PRIORITY

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E.O. 11652: N/A

TAGS: OGEN,ETRD,TBIU,CI,DR,ES,GT,HA,HO,MY,NU,PE,SN,UY

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES
AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-212-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

(A) NOVOCAIN 2 PERCENT (BRAND OF PROCAINE HCL)

PONTOCAINE HCL 0.15 PERCENT (BRAND OF TETRACAINE HCL)

WITH NEO-COBEFRIN 1:20,000 (BRAND OF LEVONORDEFIN COOK-

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WAITE LABORATORIES, INC., NY, NY; INJECTABLE; 2.2 ML.

CARTRIDGE; 50 CARTRIDGES PER CAN.

(B) CARTUCHO COOK (PROCAINA, PETRACAINA Y NEO-NORDEFINA);
WINTHROP PRODUCTS, INC., NUEVA YORK, NY; INJECTABLE;
50/1.8 ML. CARTRIDGES PER CAN.

(C) A.B. CARPULE, NOVOCAIN 2 PERCENT, PONTCAINE
0.15 PERCENT, NEO-COBEFRIN 1:20,000; WINTHROP PRODUCTS,
INC., NUEVA YORK, NY; INJECTABLES; 50/1.8 ML. CARTRIDGES
PER CAN.

LOT NUMBERS:

THESE PRODUCTS HAVE LOT NUMBERS CONSISTING OF THREE
LETTERS FOLLOWED BY 2 DIGITS. ALL LOTS OF CARTRIDGES
WITH AN "L" IN THE SECOND POSITION ARE BEING RECALLED.
ALSO, ALL LOTS WITH THE FOLLOWING COMBINATIONS IN THE
FIRST TWO POSITIONS ARE BEING RECALLED: AN, CN, LN, PN,
RN, UN.

MLE01 UNE01 PNE01

CNE01 MLE02
CNE02 ULE01

PNE02 TLE01

DISTRIBUTION: FROM 1/1/74 UNTIL 8/18/75

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVE.
RENSSELAER, NY 12144

RECALLING FIRM:

A.
COOK-WAITE LABORATORIES, INC.
90 PARK AVE.
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NY, NY 10016

B.
WINTHROP PRODUCTS
90 PARK AVE.
NY, NY 10016

REASON FOR ADVISORY (RECALL):

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES
HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA

ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN
MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANU-
FACTURING PRACTICE REGULATIONS AND THAT THERE WAS A
QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE
MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF

"STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL OF
THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES
TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAILS
OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL
CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS
ON AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS
MAY ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL
AUTHORITIES INFORMING THEM OF THE RECALL SO THAT THEY
MAY TAKE SUCH ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

- A. (THE SIDNEY ROSS COM, Y ZIA (LTD), SANTIAGO, CHILE
(CARTUCHO COOK NO. 2).
 - B. STERLING PRODUCTS INTERNATIONAL, INC., SANTO DOMINGO,
DOMINICAN REPUBLIC (ABC CARPULES).
 - C. CENTRAL AMERICAN ADMINISTRATION, STERLING PRODUCTS
INTERNATIONAL, INC., CAA, SAN SALVADOR, EL SALVADOR, CA
(CARTUCHO COOK).
 - D. STERLING PRODUCTS INTERNATIONAL SA, GUATEMALA CITY,
GUATEMALA (CARTUCHO COOK).
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- E. STERLING PRODUCTS INTERNATIONAL SA, TEGUCIGALPA,
DC HONDURAS (CARTUCHO COOK).
- F. SIDNEY ROSS, SA, LIMA, PERU (CARTUCHO COOK)
- G. SIDNEY ROSS URUGUAY LIMITADA, MONTEVEDEO, URUGUAY
(CARTUCHO COOK).
- H. STERLING DRUG (SINGAPORE) LTD., SINGAPORE (RPN)
- I. STERLING DRUG (MALAYA) SBN. BHD. JULAN GURNEY,
KUALA LUMPUR, MALAYSIA (RPN).
- J. MR. JEAN CRAAN, PORT-AU-PRINCE, HAITI (RPN)
- K. LABORATORIOS PHARMACEUTICOS DE NICARAGUA, SA,
MANAGUA, NICARAGUA (CARTUCHO COOK). INGERSOLL

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Message Attributes

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Margaret P. Grafeld
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EO Systematic Review
04 MAY 2006

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TAGS: OGEN, ETRD, TBIO, CI, DR, ES, GT, HA, HO, MY, NU, PE, SN, UY
To: SANTIAGO MULTIPLE
Type: TE
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